Remarks

Extension of Time

Accompanying this response is a Petition and Fee extending time for response by one month from December 20, 2007 to January 20, 2008. Inasmuch as January 20, 2008 is a Sunday and January 21, 2008 is a Federal holiday, the actual response is not due until January 22, 2008.

Amendments

Independent claims 1 and 18 have been amended, without prejudice, to make explicit the requirement that a ***hydrophobic*** surface has a contact angle greater than 90°. No new matter has been added inasmuch as the specification (page 7, lines 3-4) states that a hydrophobic layer "presents a low-energy surface (contact angle > 90°) to any body fluid 40 it contacts."

In addition, independent claim 18 has been amended, without prejudice, to include features of a preferred embodiment of Applicants' invention; to wit, the features emphasized in bold-face, italics below:

(1) a region of said at least one surface including an array of ***pillar-like*** [e.g., FIGs. 1-7, 9-10; specification, page 4, lines 24-26] microstructures or nanostructures that covers first portions of said surface, said array rendering the region to have a dynamically controllable hydrophobicity ***between a first state, in which said fluid is suspended over the top of said microstructures or nanostructures*** [e.g., FIGs. 1, 3, 9 (tile 90.J); specification, page 5, lines 20-28; specification, page 7, lines 18-29]***, and a second state, in which said fluid penetrates the interstices of said microstructures or nanostructures*** [FIGs. 2, 9 (tile 90.K); specification, page 5, lines 20-28; specification, page 7, lines 18-29];

(2) a medicinal substance adhered to an exposed second portion of said surface ***located in said interstices of said microstructures or nanostructures*** [e.g., FIG. 3, medicinal substance 69; specification, page 6, lines 18-30]; and

(3) a control device affixed to said tubular member for applying a voltage between said fluid and said substrate to vary said hydrophobicity, thereby releasing said substance into said body fluid ***when in said second state*** [specification, page 7, lines 18-29], said device being

actuatable from an *ex vivo* source.

Support for each of the changes to claim 18 (shown in bold-face, italics text) is indicated by cross-references to the figures and specification (shown in brackets). It should be clear, therefore, that no new matter has been added.

Summary of the Invention

Before discussing the rejection on the merits, it will be helpful to briefly review Applicants' invention.

In one aspect of the invention, as set forth in both independent claims 1 and 18, a stent comprises a tubular member having an interior surface and an exterior surface, with a region of at least one of the ***surfaces*** being ***hydrophobic***; that is, the surface has a contact angle greater than 90°. The ***hydrophobic surface*** region is provided with an array of microstructures or nanostructures that covers first portions of the surface but leaves second portions exposed in the interstices of the array. These structures cause the region to have a ***dynamically controllable*** hydrophobicity.

In one embodiment, a control device, which is affixed to the tubular member, varies the surface hydrophobicity of the region (claim 2; claim 18, lines 29 ***et seq.***). In another embodiment, which is particularly applicable to the delivery of a medicinal substance (e.g., a chemically active agent such as pharmacological agent or drug) to fluids in body vessels, the stent also includes such a medicinal substance that adheres to the exposed portions until the control device alters the hydrophobicity of the region and causes the substance to be released into the body fluid in contact with the stent (claims 5-7; claim 18, lines 29 ***et seq.***). In still another embodiment, the control device is remotely actuated from a source located external to the body (claim 4; claim 18, page 5, line 2).

In still another aspect of the invention, the hydrophobic surface region is ***tiled***; that is, divided into at least first and second zones whose surface hydrophobicity is separately controllable, so that, for example, chemically active (e.g., medicinal) substances adhered to those zones may be selectively released (claim 9; claim 19). The same substances, with the same or different dose, may be adhered to the first and second zones (claim 10; claim 20), or different

substances may be adhered to the first and second zones (claim 11; claim 21).

Claim Rejections – 35 USC §102

Claims 1-8, 12-13 and 18-20 have been rejected under 35 USC §102(b) as being anticipated by S. R. Bailey ***et al.***, International Application Publication No. WO 02/064019, which was published on August 22, 2002 (hereinafter ***Bailey***).

Claims 1-2, 5-7 and 9-11 have been rejected under 35 USC §102(e) as being anticipated by C. Momma ***et al.***, US Patent Application Publication No. 2005/0027350, which was published on February 3, 2005 based on an application filed on July 30, 2003 (hereinafter ***Momma***).

Claims 1-2, 5-7 and 15-17 have been rejected under 35 USC §102(e) as being anticipated by V. P. Shastri ***et al.***, US Patent Application Publication No. 2004/0115239, which was published on July 17, 2004 based on an application filed on September 22, 2003 (hereinafter ***Shastri***).

Claims 1 and 14 have been rejected under 35 USC §102(b) as being anticipated by H. S. Oktay, US Patent Application Publication No. 2003/0040791, which was published on February 27, 2003 based on an application filed on August 22, 2002 (hereinafter ***Oktay***).

These rejections are respectfully traversed for ***any one or more*** of the reasons set forth below.

(1) **Anticipation:** The law of anticipation under Section 102 is clear, as set forth in MPEP 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ...claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). ***Each and every element*** of Applicants' claims is ***not*** found in either Bailey, or Momma, or Shastri, or Oktay, as discussed below.

(2) **Surface Hydrophobicity-Standard Definition:** The standard, well known definition of ***hydrophobicity*** is illustrated in the attached article from ***Wikipedia***, which describes the phenomenon of ***wetting*** as the "contact between a liquid and a solid surface." The article also states that the "degree of wetting is described by the contact

angle" and that a "contact angle of 90° or greater generally characterizes a surface as not-wettable, and one less than 90° as wettable. In the context of water, a wettable surface may also be termed ***hydrophilic*** and a not-wettable surface ***hydrophobic***." Thus, the article clearly teaches that a hydrophobic surface is not wettable and, therefore, has a contact angle greater than 90° to water. Applicants' use of the term follows this standard definition; that is, Applicants' specification (page 5, line 21) explicitly states that a hydrophobic surface is "a low-energy surface that is characterized by a high contact angle (> 90°) to any body fluid it contacts." (This limitation is now explicit in independent claims 1 and 18.) Since it is notoriously well known that body fluids, such as blood, are aqueous, it follows that the standard definition of ***hydrophobic*** is equally applicable to Applicants' invention.

(3) **Surface Hydrophobicity-Examiner's Definition:** In his Response to Arguments (Office action, pages 4-5) the Examiner asserts, without support, that Applicants have adopted a "special definition" of hydrophobic. To the contrary, as paragraph (2) above demonstrates, Applicants' definition of hydrophobic is consistent with the standard definition well known in the art. In addition, the Examiner asserts that he is "entitled to give terms in a claim its (***sic***) plain meaning as interpreted by one of ordinary skill in the art." However, the Examiner has provided ***no evidence*** of this "plain meaning as interpreted by one of ordinary skill in the art." Instead, he attempts to imbue a set of references, which are ***silent*** on the matter of hydrophobicity, with an unsupported notion that they inherently "disclose materials for the stent surfaces that clearly have a low affinity for water or are ***in other words hydrophobic***." The Examiner continues this fallacious argument by asserting that the failure of stent materials (mostly metals) to ***absorb*** body fluids somehow makes them hydrophobic. However, as discussed in paragraph (2) above, absorption is not part of the definition; having a contact angle greater than 90° defines makes a surface hydrophobic (claims 1 and 18).

(4) **Surface Hydrophobicity-Metals:** The Examiner's position on Bailey typifies his position; to wit, metals don't absorb; therefore, metals must be hydrophobic. This

argument contravenes the standard definition of hydrophobicity, as discussed in paragraph (2) above. Second, the prior art teaches that the contact angles of illustrative clean metal surfaces are hydrophilic, not hydrophobic; that is, they have contact angles less than 90° (Au ~ 71°; Pt ~ 0°; stainless steel < 5°). Thus, the Examiner's ***unsupported assumption*** is without foundation in the art.

(5) **Dynamically Controllable Hydrophobicity-General:** Applicants' invention requires that the surface hydrophobicity is ***dynamically controlled*** (claim 1, lines 7-8; claim 18, lines 23-24). To this end, various embodiments of Applicants' invention include an array of nanostructures (or microstructures; claim 1, lines 6-7; claim 18, lines 22-23) in a first portion of the surface and a control device affixed to the tubular member for varying the hydrophobicity (claim 2; claim 7; claim 18, lines 29 ***et seq.***). Even assuming, ***arguendo***, that the references relate to surface hydrophobicity, none describes the dynamic control of that hydrophobicity.

(6) **Dynamically Controllable Hydrophobicity-Specific:** In a preferred embodiment of Applicants' invention, as set forth in claim 18, a combination of additional novel features gives rise to patentability, including: (i) an array of ***pillar-like*** microstructures or nanostructures (claim 18, lines 22-23); (ii) dynamically controllable hydrophobicity between a first state, in which the body fluid is suspended over the top of the microstructures or nanostructures, and a second state, in which the fluid penetrates the interstices of the microstructures or nanostructures (claim 18, lines 24-26); (iii) a medicinal substance located in the interstices (claim 18, lines 27-28); and (iv) a control device causing the release of the medicinal substance when in the second state (claim 18, page 2, lines 1-2). This combination of features is neither taught nor suggested by the art of record. Therefore, claim 18, and claims 19-21, which depend therefrom, are patentable not only by virtue of their inclusion of a hydrophobic surface, as discussed in paragraphs (2)-(5) above, but also because of the specifically-defined control of that hydrophobicity, as discussed in this paragraph.

(7) **Dynamically Controllable Hydrophobicity-Bailey:** In Bailey, the Examiner states "Another stent is also disclosed that describes an array of microstructures or grooves

and hydrophobicity can be controlled in a dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects (*sic*) hydrophobicity." However, this section of Bailey merely describes an endoluminal implant having a plurality of microgrooves on the luminal and/or abluminal surfaces thereof which facilitate improved endothelialization over a non-grooved implant. The Examiner's bald assertion that these grooves and/or the cellular response to them "clearly effects (*sic*) hydrophobicity" is pure speculation. Bailey does not describe a hydrophobic surface; nor is such a surface inherent in his device. In addition, even assuming, ***arguendo***, that a hydrophobic surface were present, Bailey fails to teach that the grooves would be used to dynamically control such hydrophobicity. No such control is described.

(8) **Variable Penetration of Interstices:** Claim 8 calls for a control device that varies the "penetration of the interstices of said array by said fluid, thereby causing release of said agent or drug into said fluid." Claim 18 has a similar requirement at lines 24-26. This feature has not been addressed by the Examiner in his rejection of claims 8 and 18 in view of Bailey. Consequently, a ***prima facie*** case of anticipation has not been established. For the record, however, Bailey is totally devoid of any teaching of this control feature, which enables Applicants' array to control surface hydrophobicity and, in turn, the release of agents/drugs located in the interstices.

(9) **Dynamically Controllable Hydrophobicity-Momma:** The Examiner asserts that FIG. 2 of Momma "shows a stent body 42 that includes an array (*sic*) microstructures 38 and control device in the form of a membrane 46 to vary hydrophobicity." First, contrary to the Examiner's unsupported assertion, the mere fact that Momma's stent is a metal does not make the metal surface hydrophobic, as discussed in paragraphs (2)-(4) above. Second, even assuming, ***arguendo***, that a hydrophobic surface were present, there is no evidence that Momma's array of raised micro-channels 38 would affect surface hydrophobicity. Third, element 46 is merely a biodegradable cover layer that releases underlying active substance 44 into blood vessel media 22. Momma provides no teaching that cover layer 46 has any effect, no less control, of

surface hydrophobicity, as required by claim 1.

(10) **Dynamically Controllable Hydrophobicity-Shastri:** The Examiner points to Shastri's disclosure that "fibers or particles of nanosize" are "placed on the surface of an implant" and chemically active substances can be used on the device with control devices (polymer materials). These [control devices?] "include cells that change the surface properties or hydrophobicity." Then, the Examiner concludes that "Shastri discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to be synonymous with hydrophobicity." First, Shastri fails to teach a hydrophobic surface, as discussed in paragraphs (2)-(4) above. Second, the Examiner's interpretation that "wettability [is] synonymous with hydrophobicity" is contrary to the standard definition of these terms, as discussed in paragraph (2) above. Third, even assuming, ***arguendo***, the presence of a hydrophobic surface, there is no evidence that Shastri's particles and/or cells affect surface hydrophobicity. Fourth, the Examiner references paragraphs 75, 79, 82 and 84 of Shastri to show that "chemically active substances can be used on the devices with control devices (polymer materials)," but there is no evidence in these paragraphs that any such device controls the surface hydrophobicity of Shastri's deposited particle layer.

(11) **Dynamically Controllable Hydrophobicity-Oktay:** The Examiner asserts that Oktay's FIG. 10 shows "a stent 1000 with an array of microstructures 1050, 1060 on a region of the stent." However, the elements 1050, 1060 are, in fact, MEMS motors, not microstructures capable of controlling hydrophobicity. Next, the Examiner asserts that "Oktay discloses (paragraph 69) the stent structure is made of metal and ***thus is hydrophobic.*** As discussed in paragraphs (2)-(4), however, the Examiner's logic fails when tested in the light of the standard definition of hydrophobic and the known ***hydrophilic*** nature of metals.

(12) **Tiled Hydrophobic Surface:** Claims 9 and 19 recite a stent design in which the array of nanostructures/microstructures covers first portions of the stent surface, and second portions (e.g., the interstices of the array) remain exposed. This exposed portion is ***tiled*** in this embodiment of the invention; that is, divided into electrically

isolated first and second zones, which have chemically active substances adhered thereto. The control device actuates the release of the substances from the zones. In this regard, the Examiner has cited Bailey against claim 19 and Momma against claim 9. However, in applying Bailey to claim 19, the Examiner does not explicitly address the separate control of tiled, isolated surface zones leading to the controlled release of substances from predetermined zones. Thus, a ***prima facie*** case of anticipation of claim 19 in view of Bailey has not been made out. Likewise, what Momma teaches in this regard is quite different from Applicants' invention, as defined by claim 9. Momma's approach to the release of multiple, different substances is evident from FIG. 2, which shows two active substances 52, 54 ***stacked*** on top of one another at the ***same*** implantation site. The upper active substance 54 is covered by a biodegradable layer 46, and the lower active substance 52 is covered by a biodegradable layer 50, which also separates the two active substance layers 52, 54 from one another. Over time the upper cover layer 46 biodegrades releasing upper active substance 54. Later, the lower cover layer 50 biodegrades releasing lower active substance 52. Note, the biodegradation of cover layers 46, 50 is a ***passive*** function; it not ***dynamically*** controlled by an ***ex vivo*** source as required by claim 9. In addition, claim 9 requires that the ***exposed portion of the hydrophobic surface is electrically isolated into first and second spatial zones*** containing a chemically active substance (i.e., the surface is ***tiled*** into separately controllable zones), and the control device is capable of causing separate release of the substances from the first and second zones at different times. Clearly, for each micro-channel 38 Momma's stacked, active substances are disposed in/above the ***same zone of the surface***, not in ***different*** surface zones, and Momma's control of the release of the substances is passive not dynamic.

In view of the foregoing it is respectfully submitted that claims 1-21 are not anticipated by Bailey, Momma, Shastri or Oktay.

Claim Rejections – 35 USC 103

Claim 21 has been rejected under 35 USC 103(a) as being unpatentable over Bailey in view of Momma. However, this rejection is predicated on the notion that all of the limitations of independent claim 21 are taught by Bailey except for "different substances to be released into the implantation site."

This rejection is respectfully traversed. Note, first, that claim 21 depends from claim 18. Second, as argued in paragraph (6) above with reference to the Section 102 rejections based on Bailey, which arguments are incorporated herein by reference, claim 18 includes several fundamental, patentably distinguishing features (including those related to the dynamic control of surface hydrophobicity) that are not disclosed by Bailey. Moreover, these deficiencies are not remedied by Momma. Accordingly, claim 21, which depends from claim 18, is likewise patentable.

In addition, however, even assuming, ***arguendo***, that the Examiner's position on Bailey is correct, his further reliance on Momma is misplaced. More specifically, the Examiner makes the following assertions:

> Momma et al. teach different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21, 45. It would have been obvious...to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey...

What Momma teaches in this regard, however, is quite different from Applicants' invention. Momma's approach to the release of multiple, different substances is evident from FIG. 2, which shows two active substances 52, 54 ***stacked*** on top of one another at the ***same*** implantation site. The upper active substance 54 is covered by a biodegradable layer 46, and the lower active substance 52 is covered by a biodegradable layer 50, which also separates the two active substance layers 52, 54 from one another. Over time the upper cover layer 46 biodegrades releasing upper active substance 54. Later, the lower cover layer 50 biodegrades releasing lower active substance 52. Note, the biodegradation of cover layers 46, 50 is a ***passive*** function; it not ***dynamically*** controlled by an ***ex vivo*** source as required by claim 18, line 19. In addition, claims 18-19, from which claim 21 depends, require that the ***exposed portion of the hydrophobic surface is electrically isolated into first and second spatial zones*** containing a medicinal

substance (i.e., the surface is ***tiled*** into separately controllable zones), and the control device is capable of causing separate release of the substances from the first and second zones (claim 19). Claims 21 requires that the medicinal substances adhered to the first and second surface zones are different substances. Clearly, for each micro-channel 38 Momma's stacked, active substances are disposed in/above the ***same zone of the surface***, not in ***different*** surface zones, and Momma's control of the release of the substances is passive not dynamic.

Accordingly, it is respectfully submitted that the combination of Bailey and Momma fail to render obvious Applicants' invention as defined by claim 21.

Conclusion

In view of the foregoing, reconsideration of claims 1-21, and passage of this application to issue, are hereby respectfully requested. If during the consideration of this paper, the Examiner believes that resolution of the issues raised will be facilitated by further discussion, she is urged to contact the undersigned attorney at 610-691-7710 (voice) or 610-691-8434 (fax).

Respectfully,

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Date: 01/21/08

Wetting

Application SN 10/798,064
Arney 10-18-4

From Wikipedia, the free encyclopedia

Wetting is the contact between a liquid and a solid surface, resulting from intermolecular interactions when the two are brought together. The amount of wetting depends on the energies (or surface tensions) of the interfaces involved such that the total energy is minimized. The degree of wetting is described by the contact angle, the angle at which the liquid-vapor interface meets the solid-liquid interface. If the wetting is very favorable, the contact angle will be low, and the fluid will spread to cover a larger area of the surface. If the wetting is unfavorable, the fluid will form a compact droplet on the surface. Regardless of the amount of wetting, the shape of a drop wetted to a rigid surface is roughly a truncated sphere. Various degrees of wetting are depicted in Figure 1.

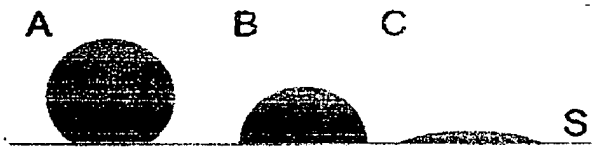

Figure 1: Wetting of different fluids. *A* shows a fluid with very little wetting, while *C* shows a fluid with more wetting. A has a high contact angle, and C has a small contact angle.

A contact angle of 90° or greater generally characterizes a surface as not-wettable, and one less than 90° as wettable. In the context of water, a wettable surface may also be termed hydrophilic and a non-wettable surface hydrophobic. Superhydrophobic surfaces have contact angles greater than 150°, showing almost no contact between the liquid drop and the surface. This is sometimes referred to as the "Lotus effect". Wetting is also important in the bonding or adherence of two materials. Wetting and the surface forces that control wetting are also responsible for other related effects, including so-called capillary effects.

Contents

Minimization of energy, three phases

Consider the line of contact where three phases meet, as shown in Figure 2. In equilibrium, the net force per unit length acting along the boundary line between the three phases must be zero. The components of net force in the direction along each of the interfaces are given by:

$$\gamma_{\alpha\theta} + \gamma_{\theta\beta}\cos\theta + \gamma_{\alpha\beta}\cos\alpha = 0$$
$$\gamma_{\alpha\theta}\cos\theta + \gamma_{\theta\beta} + \gamma_{\alpha\beta}\cos\beta = 0$$
$$\gamma_{\alpha\theta}\cos\alpha + \gamma_{\theta\beta}\cos\beta + \gamma_{\alpha\beta} = 0$$

where α, β, and θ are the angles shown and γ_{ij} is the surface energy between the two indicated phases.

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ARTIFACT OF FACSIMILE MACHINE

OF M. J. URBANO